

### **REMARKS**

Applicants respectfully request entry of amendments to claims 1, 15, 19, 22, 31, 33, and 37. Support for the amendments can be found throughout the specification, including page 17, ll. 8-20, page 59, ll. 25-31, and the originally filed claims and, therefore, do not add new matter.

Applicants submit that pending claims 1, 9-11, 15, 19, 22, 26-29, 31-33, 37, and 39-43 are in condition for allowance, or are in better condition for presentation on appeal, and respectfully request that the claims as amended be entered.

### **Rejection Under 35 U.S.C. §102**

Claims 1, 9-11, 15, 19, 22, 27-29, 31-33, 37, 39-40, 42, and 43 stand rejected under 35 U.S.C. §102(e), as allegedly being anticipated by Barker et al.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that the cited reference is available as prior art because the elements as recited in the present claims do not enjoy the priority date of U.S. Ser. No. 09/124,180 (hereinafter, the '180 application). Applicants have amended the claims such they no longer recite piscine species sequences. However, with regard to the remaining sequence elements, Applicants submit that such elements enjoy the priority date of the '180 application; i.e., July 28, 1998.

The present claims expressly recite "amino acid residues from about 1-20" of the sequence elements as listed. Explicit support for this element comes directly from Figures 6A and 6B, as well as page 44, l. 3 bridging to page 45, l. 2 of the '180 application. The figures graphically demonstrate that residues 1-20, for both murine and human GDF-8 homologs, have the same hydrophobicity profile and contain "a core of hydrophobic amino acids at the N-terminus suggestive of a signal peptide for secretion." (See, e.g., page 44, ll. 10-11 and ll. 23-24). Further, as the sequence identity between the first 20 amino acids for the sequences listed in the claims is highly conserved (e.g., comparing SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14 and 16 of present application or SEQ ID NOS: 12, 14, 19, 21, 23, 25, 27, and 29 of the '180 application), they would all be expected to possess the same hydrophobic properties/signal peptide identity. Thus,

as the element "said peptide having a core of hydrophobic amino acids . . . corresponding to amino acids residues 1-20 of the full length promyostatin polypeptide" is taken directly from the '180 application specification, this element enjoys the priority date of the '180 application.

Regarding claims 33 and 37, while not acquiescing to the reasoning offered in the Action, and to expedite prosecution towards allowance, the claims no longer recite the element at issue. However, the claims now recite either residues 1-262 or 263 (claim 33) or 1-262 (claim 37). Support for these elements in the '180 application may be found in Figure 12a, which shows a polynucleotide comprising a promyostatin prodomain corresponding to the residues as recited: i.e., the targeting construct. This construct is devoid of the C-terminal region of GDF-8 (see, e.g., page 50, ll. 3-5 of the '180 application) and comprises the prodomain as claimed. Thus, as the element "1-262" is taken directly from the '180 application specification, this element enjoys the priority date of the '180 application.

Regarding the elements for claims 19, 22, and 42-43, the recitation "from about 267 or 268 to 374 or 375" is provided to delimit the C-terminal fragment for GDF-8. This element finds support in Example 5 of the '180 application (i.e., page 46, l. 19 bridging to page 47, l. 7), which demonstrates that this region of GDF-8 is the proper post-translationally modified product secreted from cells transfected with a murine GDF-8 cDNA clone. Further, that this fragment possesses muscle cell growth regulatory activity is provided in Example 8 (in its entirety), which shows that when this region is deleted in GDF-8 knockout mice, homozygous mutant mice were 30% larger. Moreover, at page 54, ll. 5-11 of the '180 application, it is expressly stated that the C-terminal region between the recited species shows absolute conservation. Thus, as the element "said peptide having muscle growth inhibitory activity comprising a promyostatin myostatin domain corresponding to amino acid residues from about 267 or 268 to 374 or 375 of a full length promyostatin polypeptide" is taken directly from the '180 application specification, this element enjoys the priority date of the '180 application.

Therefore, as the elements of the instant amended claims enjoy the benefit of priority of the '180 application, the effective date for the instant amended claims is July 28, 1998. Because Barker et al. was filed on February 18, 1999, the reference is not available as prior art.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

In re Application of:  
Lee and McPherron  
Application No.: 09/708,693  
Filing Date: November 7, 2000  
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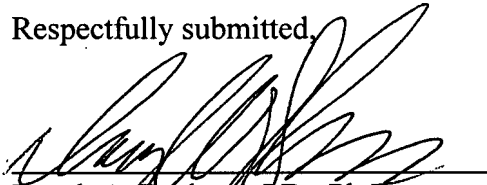
PATENT  
Attorney Docket No. JHU1120-15

**Conclusion**

Applicants submit that pending claims 1, 9-11, 15, 19, 22, 26-29, 31-33, 37, and 39-43 are in condition for allowance, or are in better condition for appeal. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

No fee is deemed necessary with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees required by this submission, or credit any overpayments, to Deposit Account No. 07-1896 referencing the above-identified docket number. A copy the Transmittal Sheet is enclosed.

Respectfully submitted,



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